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Substitute for form 14495 PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

Date Submitted: March 8, 2004

(use as many sheets as necessary)

Sheet 1 of 4

Complete If Known

Application Number	10/713,149
Filing Date	11/17/2003
First Named Inventor	Robert H. GETZENBERG
Group Art Unit	2611
Examiner Name	Not yet assigned
Attorney Docket Number	076333-0331

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code ² (if known)			
PR	4,882,268			Penman et al.	11/21/89	
PR	5,273,877			Fey et al.	12/28/93	
PR	5,849,509			Coffey et al.	12/15/98	
PR	5,866,535			Getzenberg et al.	2/2/99	
PR	4,885,236			Penman et al.	12/5/89	
PR	5,824,490			Coffey et al.	10/20/98	
PR	5,547,928			Wu et al.	08/20/96	
PR	6,232,443			Getzenberg	3/1998	
PR	5,989,826			Beausang et al.	11/23/1999	
PR	6,162,608			Beausang et al.	12/19/2000	
PR	6,410,247			Beausang et al.	6/25/2002	
PR	Re 35,747			Penman et al.	3/17/1998	

FOREIGN PATENT DOCUMENTS

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		Office ³	Number ⁴	Kind Code ⁵ (if known)				
		WO	95/16919			6/22/95		
		WO	93/09437			5/18/93		
		WO	94/00573			1/16/94		
		WO	87/03910			7/2/87		
		WO	94/10222			8/18/04		
		WO	97/10200			8/5/07		

NON PATENT LITERATURE DOCUMENTS

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		Miyanaga N. et al., "Nuclear Matrix Proteins as a Urine Marker for Transitional Cell Carcinoma of the Bladder", The Journal of Urology Supplement, Vol. 153, No. 4 (XP-002068914)	
		Mermel S. et al., "The Performance of the NMP22™ Test Kit: A Quantitative Enzyme Immuno-Assay for Bladder Cancer", Tumor Biology, 17 (suppl 1)(1996) (XP-002068915)	
PR		Getzenberg, R. et al., "Bladder Cancer-associated Nuclear Matrix Proteins", Cancer Research Vol. 56, No. 7, pp. 1690-1694, (1996). (XP-002068894).	
PR		Konety, B.R., Identification of Nuclear Matrix Protein Alterations Associated with Renal Cell Carcinoma", The Journal of Urology, Vol. 159, No. 4, pp. 1359-1363 (1998). (XP002068895).	

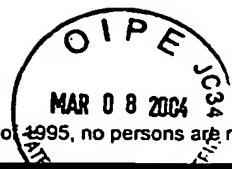
Examiner Signature	/Peter Reddig/	Date Considered	12/18/2006
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MODIFIED PTO/SB/08 (08-00)

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U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

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Substitute for form 1449B PTO <i>DEMAK TAK</i>				Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Application Number	10/713,149
Date Submitted: March 8, 2004 <i>(use as many sheets as necessary)</i>				Filing Date	11/17/2003
				First Named Inventor	Robert H. GETZENBERG
				Group Art Unit	2611
				Examiner Name	Not yet assigned
Sheet	2	of	4	Attorney Docket Number	076333-0331

NON PATENT LITERATURE DOCUMENTS					
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.			
		Eberharten A., et al., "Nuclear Matrix of the Lower Eukaryote Physarum Polyccephalum and the mammalian epithelial LLC-PK1 cell line—A comprehensive investigation of different preparation procedures", Vol. 212, No. 2, pp. 573-580 (1992). (XP02068893).			T ⁶
		Keesee S.K. et al. "Utilization of Nuclear Matrix Proteins for Cancer Diagnosis". Critical Reviews in Eukaryotic Gene Expression", Vol., 6, No. 2&3, pp. 189-214 (1996). (XP002069158).			
		Getzenberg, R.H., "Nuclear Matrix and the Regulation of Gene Expression. Tissue Specificity", Journal of Cellular Biochemistry, Vol. 55, pp. 22-31 (1994).			
		Getzenberg, R.H. et al., "Identification of Nuclear Matrix Proteins in the Cancer and Normal Rat Prostate", Cancer Research, Vol. 51, pp. 6514-6520 (1994).			
		Borenzow, R. et al., "Identification of a Nuclear Protein Matrix", Biochemical and Biophysical Research Communications, Vol. 60, No. 4 (1974).			
		Fey, E.G. et al., "The Nuclear Matrix: Defining Structural and Functional Roles" Eukaryotic Gene Expression, pp. 127-143 (1991).			
		Fey E.G. et al., "Tumor promoters induce a specific morphological signature in the nuclear matrix-Intermediate filament scaffold of Madin-Darby canine kidney (MDCK) cell colonies", Proc. Natl. Acad. Sci. USA, vol. 81, pp. 4409-4413 (1984).			
		Fey E.G. et al., "Nuclear matrix proteins reflect cell type of origin in cultured human cells", Proc. Natl. Acad. Sci. USA, Vol. 85, pp. 121-125 (1988).			
		Fey E.G. et al., "Epithelial Cytoskeletal Framework and Nuclear Matrix-Intermediate Filament Scaffold: Three-dimensional Organization and Protein Composition", The Journal of Cell Biology, Vol. 98, pp. 1973-1984 (1984).			
		Weidner, N. et al., "Rapid Communication, Localization of Nuclear Matrix Proteins (NMPs) in Multiple Tissue Types with NM-200.4™ (An Antibody Strongly Reactive with NMPs Found in Breast Carcinoma)", American Journal of Pathology, Vol. 138, No. 6, pp. 1293-1298 (1991).			
		Huse, W.D. et al., "Generation of a Large Combinatorial Library of the Immunoglobulin Repertoire in Phage Lambda", Research Article, pp. 1275-1281 (1989).			
		Mullinax, R.L. et al., "Identification of human antibody fragment clones specific for tetanus toxoid in a bacteriophage λ immunoexpression library", Proc. Natl. Acad. Sci. USA, Vol. 87, pp. 8095-8099 (1990).			
		Diener F. et al. "Specific Immunosuppression by Immunotoxins Containing Daunomycin", Science Vol. 231, pp. 148-150 (1986).			
		Greiner, J.W., "Recombinant Interferon Enhances Monoclonal Antibody—Targeting of Carcinoma Lesions in Vivo", Reports, pp. 895-898 (1987).			
		Wolff B. et al., "The Use of Monoclonal Anti-Thy IgG1 for the Targeting of Liposomes to AKR-A Cells In Vitro and In Vivo", Biochimica et Biophysica Acta, Vol. 802, pp. 259-273 (1984).			

Examiner Signature	/Peter Reddig/	Date Considered	12/18/2006
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Sheet	3	of	4	Application Number	10/713,149
				Filing Date	11/17/2003
				First Named Inventor	Robert H. GETZENBERG
				Group Art Unit	2611
				Examiner Name	Not yet assigned
				Attorney Docket Number	076333-0331

NON PATENT LITERATURE DOCUMENTS					
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.			
		<u>Waintraub H.M. "Antisense RNA and DNA" Scientific American pp. 40-46 (1990)</u>			
		<u>Cech T.R. Ph.D. "Ribozymes and Their Medical Implications" JAMA, Vol. 260, No. 20, pp. 3030-3034 (1988).</u>			
		<u>Haseloff, J. et al. "Simple RNA enzymes with new and highly specific endoribonuclease activities" Nature, Vol. 334, pp. 585-591 (1988).</u>			
		<u>Bejany, D.E. et al., "Malignant Vesical Tumors Following Spinal Cord Injury", The Journal of Urology, Vol. 138, pp. 1390-1392 (1987).</u>			
		<u>Kaufman, I.M. et al. "Bladder Cancer and Squamous Metaplasia in Spinal Cord Injury Patients" pp. 967-971 (1977).</u>			
		<u>Metzak J. M.D., "The Incidence of Bladder Cancer in Paraplegia", Paraplegia, pp. 85-96.</u>			
		<u>Nyquist R.H., M.D. et al., "Mortality and Survival in Traumatic Myelof During Nineteen Years, from 1946 to 1965", Paraplegia, pp. 22-40.</u>			
		<u>Eh-Masi, W.O., "Bladder Cancer After Spinal Cord Injury", International Medical Society of Paraplegia, pp. 265-270 (1981).</u>			
		<u>Ocister, W.O., et al. "Survival in Traumatic Transverse Myelitis", Paraplegia, Vol. 14, pp. 262-275 (1977).</u>			
		<u>Hackler R.H. "A 25-Year Prospective Mortality Study In the Spinal Cord Injured Patient: Comparison With the Long-Term Living Paraplegic", The Journal of Urology, Vol. 117, pp. 486-488 (1977).</u>			
		<u>Round, C.P. et al., "Differential Nuclear Matrix Protein (NMP) Patterns In Normal Renal Tissue and Renal Cell Carcinoma (RCC)", 92nd Annual Meeting of the American Urological Association, New Orleans, LA, USA, (1997) J. of Urol. Vol. 157 (4 suppl.) (1997) (XP-002076374).</u>			
PR		<u>Konety B.R. et al., "Characteristic Nuclear Matrix Protein Alterations in Renal Cell Carcinoma (RCC)", 92nd Annual Meeting of the American Urological Association, New Orleans, LA, USA (1997), J. of Urol., Vol. 157 (4 suppl.) (1997) (XP-002076375).</u>			
		<u>Gordon, J.N. et al., "Altered Extracellular Matrices Influence Cellular Processes and Nuclear Matrix Organizations of Overlying Human Bladder Urothelial Cells", Cancer Research, Vol. 53, pp. 4971-4977 (1993).</u>			
		<u>Cupo, J. "Electrophoretic analysis of nuclear matrix proteins and the potential clinical applications", Elsevier Science Publishers B.V., pp. 389-406 (1991).</u>			
		<u>Partin, A.W. et al., "Nuclear Matrix Protein Patterns in Human Benign Prostatic Hyperplasia and Prostate Cancer", Cancer Research, Vol. 53, pp. 744-746 (1993).</u>			

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		Russell, P.J. et al. "Preclinical studies of monoclonal antibodies for intravesical radioimmunotherapy of human bladder cancer", Cell biophysics, Vols. 24/25 pp. 155-61 (1994).
		Kingsley E.A. et al., "Characterization of the anti-bladder-cancer monoclonal antibody BLCA -8: identification of its antigen as a neutral glycolipid", Cancer Immunology, Immunotherapy, Vol. 41, No. 6, pp. 348-54 (1995) (XP000872998).
		Fradet Y., "Molecular and Immunologic approaches in the management of bladder cancer", Urologic Clinics of North America, Vol. 18. No. 3, pp. 515-24 (1991) (XP000881253).
		Reprogle-Schwab R. et al., "The utilization of nuclear matrix proteins for cancer diagnosis", Critical Reviews in Eukaryotic Gene Expression, Vol. 6, Nos. 2-3, pp. 103-13 (1996), (XP000881255).
		Pirtskalaishvili G. et al., "Use of urine-based markers for detection and monitoring of bladder cancer", Techniques in urology, Vol. 5, No. 4, pp. 179-84 (1999) (XP000881344).
		J.E. Celis et al, "Expression of the transformation-sensitive protein "cyclin" in normal human epidermal basal cells and simian virus 40-transformed keratinocytes", Proc. Natl. Acad. Sci. USA, Vol. 81, pp. 3128-3132 (1984).
		J.E. Celis et al., "Intermediate filaments in monkey kidney TC7 cells: Focal centers and interrelationship with other cytoskeletal systems", Proc. Natl. Acad. Sci. USA, Vol. 81, pp. 1117-1121 (1984).
		R.G. DiScipio et al., "Nucleotide sequence of cDNA and derived amino acid sequence of human complement component C9", Proc. Natl. Acad. Sci. USA, vol. 81, pp. 7298-7302 (1984).
		R.B. Merrifield, "Solid Phase Peptide Synthesis. I. The synthesis of a Tetrapeptide", J. Am. Chem. Soc., Vol. 85, No. 14, pp. 2149-2154 (1963).
		Stewart and Young, "Solid Phase Peptide Synthesis" Freeman Publ. 1969, pp. 27-81.
		L.Y. Douillard et al., "Monoclonal Antibodies Specific Immunotherapy of Gastrointestinal Tumors" Hybridoma, Vol. 5, Suppl. 1 (1986) pp. S139-S149.
		Mabtech, NMP22® Test Kit (6/06) pp. 1-30.
		R. Fraley et al. "New Generation liposomes: the engineering of an efficient vehicle for intracellular delivery of nucleic acids", Trends Biochem. Sci., Vol. 6, pp. 77-80 (1981).
		T. Gura, Science, "Systems for Identifying New Drugs Are Often Faulty", Nov. 1997, Vol. 278, pp. 1041-1042.
		LH Hartwell et al., Science, "Integrating Genetic Approaches into the Discovery of Anticancer Drugs" Nov. 1997, Vol. 278, pp. 1064-1065.

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